

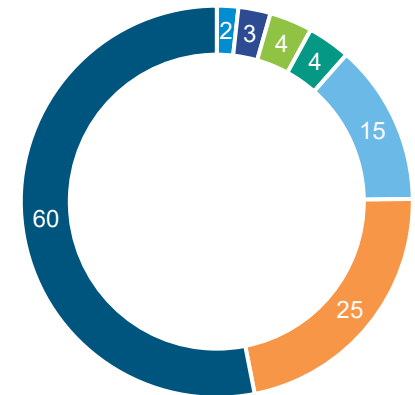
Trends in inspections of diagnostics

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Portfolio: sites and products as of 20 November 2023

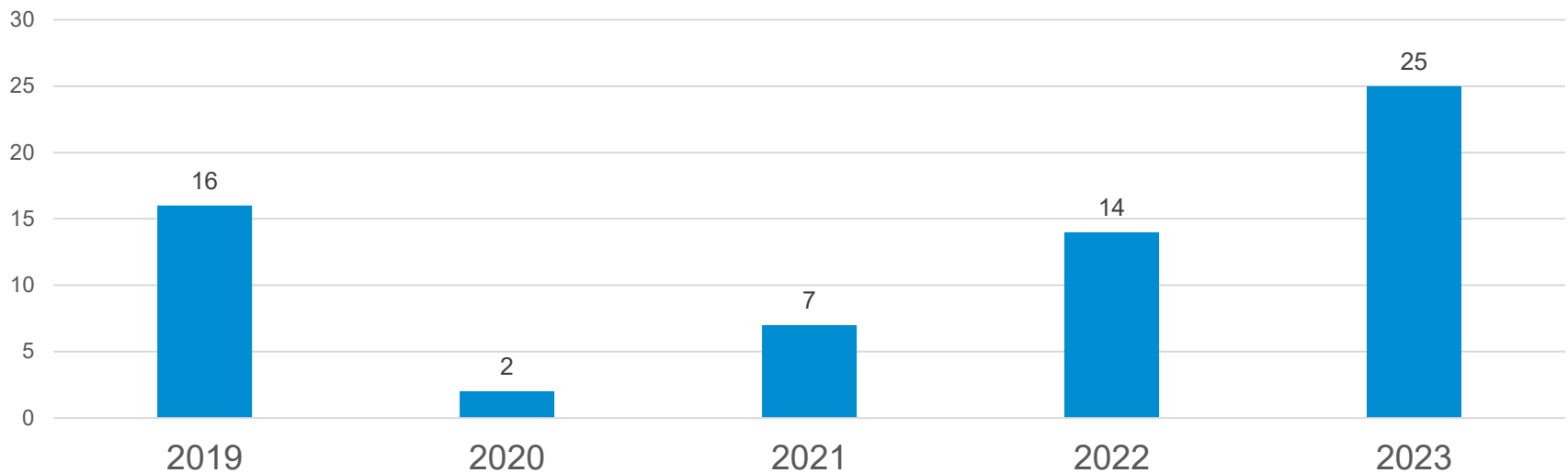


- Syphilis
- HIV Syphilis
- Hep B
- HPV
- HCV
- Malaria
- HIV

113 prequalified diagnostics products manufactured at 68 sites

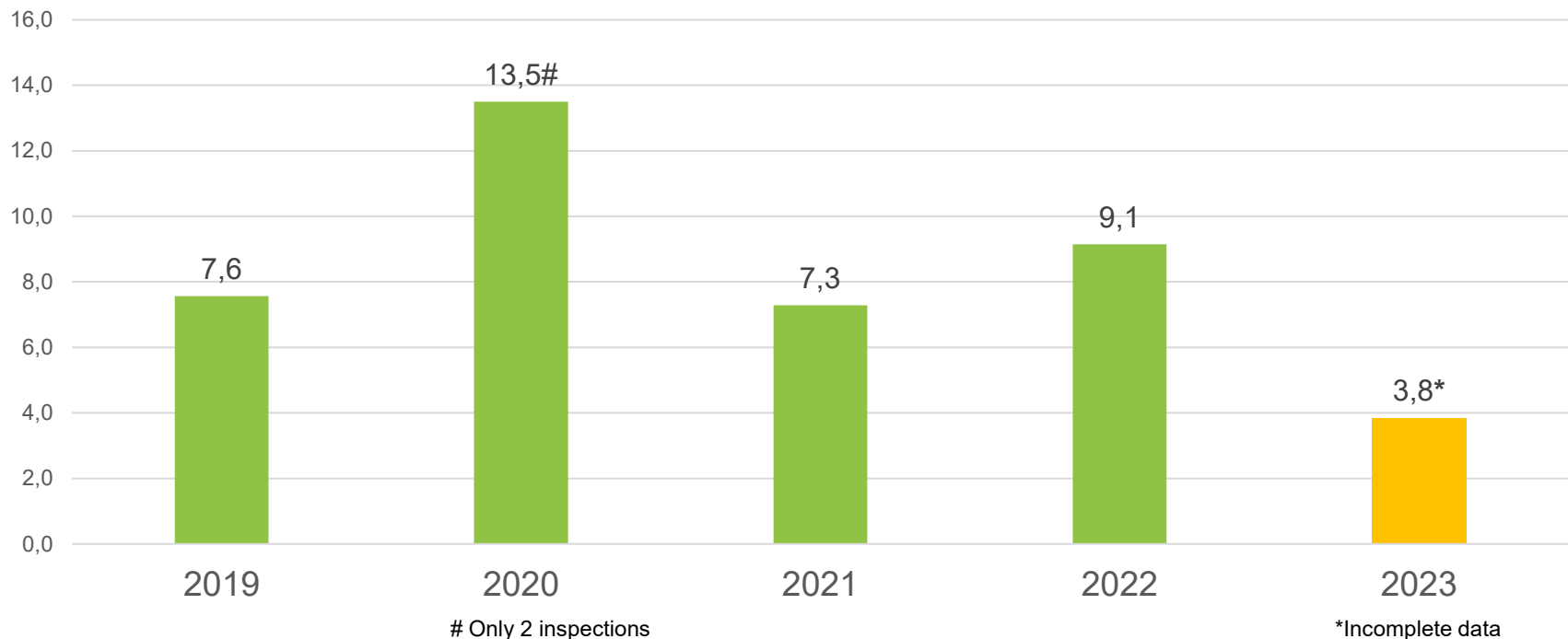
Trends in the number of onsite inspections per year

- COVID-19 pandemic prevented onsite inspections
- Backlog of onsite inspections
- Increased number of inspections/year despite stable workforce



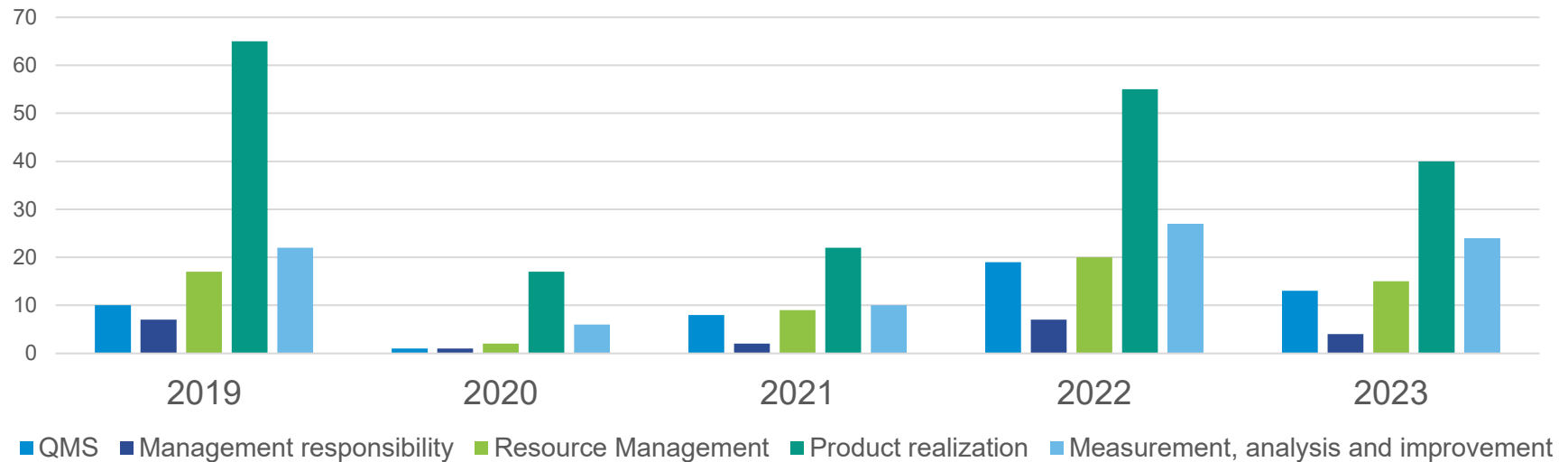
Trends in the number of nonconformities per inspection

- Relatively stable average number of NCs per inspection



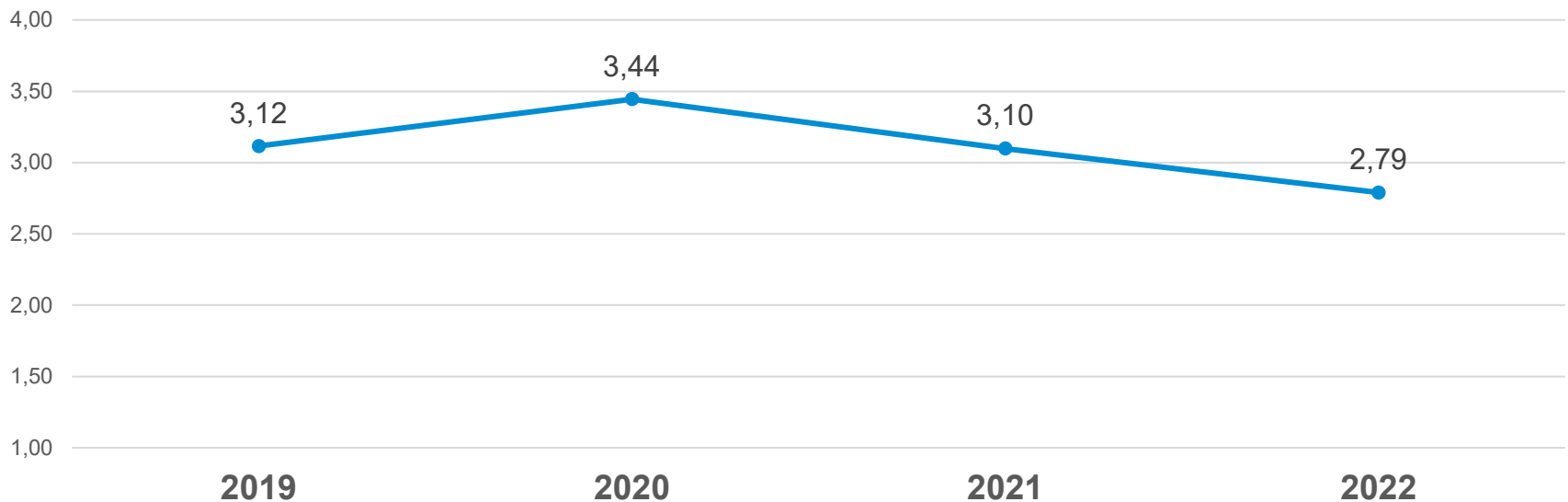
Trends in the type of non-conformities raised

- Profile of NCs raised remains constant
- Majority of NCs raised against production-related requirements
- WHO inspections complement those performed by other regulators



Trends in the mean grade of non-conformities raised

- Mean severity of non-conformities raised on a downward trend
- Impact of the program on QMS effectiveness and robustness?



Conclusions...

- COVID-related backlog being cleared
- No compromise on the quality of inspections
- Stable number and pattern of findings
- Severity of findings appear to decrease

...and Perspectives

- Continue to improve internal efficiency
- Fully implement ePQS
- Increased leveraging of reports from stringent regulatory authorities
- Welcome new sites and new products (e.g., MDR TB)



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